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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,286	BAKTHAVATCHALAM ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *186,187 and 199-216* is/are pending in the application.

4a) Of the above claim(s) *209-216* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *186,187 and 199-208* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6-7-04;12-03-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 186, 187 and 199-216 are presented for examination.

Applicants' preliminary amendment filed March 12, 2004; and information disclosure statements filed June 7, 2004 and December 3, 2004 have been received and entered.

Applicants' election filed December 6, 2004 in response to the restriction requirement of November 1, 2004 has been received and entered. The applicants elected the invention described in claims 186, 187 and 199-208 (Group I) with traverse.

Applicants' traverse of the restriction requirement is not deemed persuasive for reasons of record as set forth in the previous Office action dated November 1, 2004. Therefore, the restriction requirement is hereby made Final.

Claims 209-216 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 186, 187 and 199-208 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-185 of U.S. Patent No. 6,723,730. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented application teaches diaryl piperazine compounds and a package comprising a pharmaceutical composition containing the said diaryl piperazine compounds (A product), and the present application teaches a method of use claims containing diaryl piperazines of the patented application therein which makes the method claims of the present application an obvious variation of the patented claims.

Claims 186, 187 and 199-208 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 186, 187 and 199-208 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pain with a capsaicin receptor antagonist derived from diaryl piperazine compounds disclosed in claims 187 and 208, does not reasonably provide enablement for other capsaicin receptor antagonist. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method for treating pain in a mammal, the method comprising administering to the mammal a therapeutic dose of a capsaicin receptor antagonist that is not a capsaicin analogue.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the other capsaicin receptor antagonists beside the ones disclosed in claims 187 and 208.

The breadth of the claims

The claims are very broad and inclusive to all and any capsaicin receptor antagonist.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of diaryl piperazine compounds of the formula disclosed in claims 187 and 208.

The quantity of experimentation necessary

Applicants have failed to provided guidance as to how the other capsaicin receptor antagonists are effective in treating pain. The level of experimentation needed to determine various capsaicin receptor antagonists would be able to treat pain is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 186, 187 and 199-208 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 186, 199, 201-203, 205-207 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwak et al., "A capsaicin-receptor antagonist, capsazepine, reduces inflammation-induced hyperalgesic responses in rat: evidence for an endogenous capsaicin-like substance", Neuroscience 86(2):619-626 (1998) of PTO-1449.

Kwak et al. teach a capsaicin-receptor antagonist, capsazepine, reduces inflammation-induced hyperalgesic (pain) responses in a rat (See the abstract). As to the capsaicin receptor antagonist to exhibit no detectable agonist activity in an *in vitro* assay of capsaicin receptor agonism or is a highly potency capsaicin receptor antagonist in an *in vitro* assay of capsaicin receptor antagonism, a product of identical chemical composition or compound cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. If the prior art teaches the identical chemical structure, the properties applicants disclose and/or claims are necessary present. (In re Spada, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir., 1990). In the instant case, the aforesaid high potency in an *in vitro* assay of capsaicin receptor antagonism and non-detectable agonist activity in an *in vitro* assay of capsaicin receptor

agonism is anticipated by Kwak et al., because the reference teaches a capsaicin receptor antagonist possessing the same activity as the instant claims. To treat the various types of pain as disclosed in claims 205-207 with the capsazepine is clearly inherent since a pain-reliving compound is know to treat types and causes of pain. Clearly, the cited reference anticipates the applicants' instant invention, therefore, the instant invention is unpatentable.

Claims 186, 199, 201-203 and 205-207 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 200 and 204 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwak et al of PTO-1449.

Kwak et al. were discussed above supra for the use of a capsaicin receptor antagonist to treat pain.

The instant invention differs from the cited reference in that the cited reference does not teach the capsaicin receptor antagonist is administered five time the minimum dose needed to provide analgesia in an adult mammalian is obvious to those skilled in the pharmaceutical art. One skilled in the art would have assumed to increase the dose amount to accommodate size of the adult mammal, for example, a small frame adult may need a lower dose than a large frame adult.

Claims 200 and 204 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
April 14, 2005